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10/598,315	04/08/2008	Lawrence Solomon	SLP-035	2612

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,315	SOLOMON ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/01/07 & 06/01/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction Response

1. Applicant's election with traverse of Group I (claims 1-26 and 33) in the reply filed on January 27, 2009 is acknowledged.

The traversal is on the ground(s) that the present application is the national stage of a Patent Cooperation Treaty (PCT) Application and the provisions of Rule 13.1 of the PCT, restriction may not be required if there is a technical relationship between the claims. Applicant argues that under the ADMINISTRATIVE INSTRUCTIONS UNDER THE PCT, page AI-59, paragraph (e) (ii) of Annex B to APPENDIX T of the MPEP, a technical relation exists between a product and a process of using the product. Applicant argues that once it is established that the process uses the claimed product, division should not be required under the provisions of PCT Rule 13.2. Applicant argues that the fact that the search is not coextensive for the process and product is not a basis for requiring restriction under PCT Rule 13.2. Applicant argues that the Shah patent discloses a sustained release tablet having a minimum of exposes surface upon breaking as it is concerned with having a reduced exposed surface area at the breaking point when the tablet is broken. Applicant argues that the present invention is concerned with providing compositionally identical segments when broken.

This is not persuasive because the technical feature linking Groups I-II is a segmented tablet. Shah (US 4,824,677) teaches a segmented tablet with two or more segments that is breakable prior to administration (Abstract, Figure 1, claims 1-28). Claims 1-26 and 33 (Group I) drawn to a segmented tablet and method of using the tablet are anticipated by the disclosure of Shah and lack novelty. Therefore, the

technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Moreover, Group II requires scoring of the segmented tablet, which is not required for Group I. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

The restriction requirement is still deemed proper and is therefore made FINAL.

2. Claims 27-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

3. Claims 1-26 and 33 are included in the prosecution.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 06/01/07 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

Claim Objections

5. Claim 4 is objected to because of the following informalities: Line 7 of claim 4 has a typographical error. "… hut has fewer milligrams …" should recite "… but has fewer milligrams". Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 12-15, and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (US 4,824,677).

The claimed invention is a pharmaceutical tablet comprising a first segment one face of which is contiguous with a plurality of compositionally substantially identical unitary segments that contain a drug or drugs.

Shah teaches divisible tablets for facilitating fractional dosing of medication (Col. 1, lines 6-9). The divisible tablets "will retain their sustained release property when divided into two or more discrete segments … the sustained release characteristics of the whole tablet are retained by each segment of the tablet" (Col. 2, lines 11-20). Figures 1-7 illustrate bi-dosage divisible tablets and Figures 8 and 9 illustrate tri-dosage tablets (also Col. 3, line 6 to Col. 4, line 47). Figures 10 and 11 illustrate an elliptical bi-dosage tablet (also Col. 4, lines 48-58).

Regarding instant claims 1-2, the pharmaceutical tablet comprising a first segment one face of which is contiguous with a plurality of compositionally substantially identical unitary segments that contain a drug or drugs is anticipated by the tablets that can be divided into two or more discrete segments and where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught

by Shah (Col. 2, lines 11-20). Since each segment retains the release characteristics of the whole tablet, the tablet taught by Shah has compositionally identical segments that contain a drug or drugs. Regarding instant claim 2, the limitation of the first unitary segment and the second unitary segment being derived from the same divided layer or layers is anticipated by the area 24, which is adjacent to the common edge structure 23, as illustrated in Figure 1 by Shah.

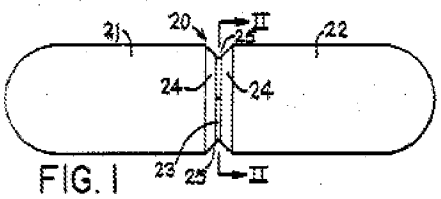

FIG. 1

Regarding instant claim 3, the one or more additional unitary segments in addition to the first and second unitary segments that are optionally present and are derived from the same layer or layers as said first unitary segment is anticipated by the two or more discrete segments of the divisible tablet, as taught by Shah (Col. 2, lines 11-20).

Regarding instant claim 5, the first unitary segment and the second unitary segment each containing a pharmacologically effective dose of the drug or drugs is anticipated by the two or more discrete segments of the divisible tablet that each retain the sustained release characteristics, as taught by Shah (Col. 2, lines 11-20). The sustained release characteristics disclosed by Shah means that drug(s) are implicitly present in each segment of the tablet and are release in a sustained manner.

Regarding instant claim 12, the limitation of the first unitary and the second unitary segments that are outer segments is anticipated by the divisible tablets

illustrated by Figures 1, 6, 8, and 10 by Shah. The divisible segments are on the outside of the tablet.

Regarding instant claim 13, the limitation of the first unitary segment and the second unitary segment adjoining other unitary segments that are outer segments is anticipated by Figure 8, as disclosed by Shah. Figure 8 illustrates three unitary segments (61, 62 and 63) and all of these are outer segments.

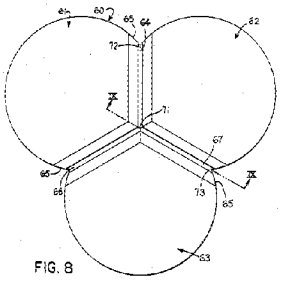

FIG. 8

Regarding instant claim 14, the limitation of interposed unitary segments between the first unitary segment and the first segment is anticipated by Figure 1 as illustrated by Shah. Unitary segments 24 are interposed between segments 21 and 22.

Regarding instant claim 15, the limitation of a substantially vertical score in said first segment, said score being vertically aligned with the center of the space between said first unitary segment and said second unitary segment is anticipated by the divisible tablet with the notch (25) located between the unitary segments (24), as illustrated in Figure 1 by Shah.

Regarding instant claims 21-22, the limitation of the first segment adjoining a plurality of unitary segments on the side of said first segment that is opposite the surface adjoining said first and second unitary segments is anticipated by the divisible tablet, as illustrated in Figure 8 by Shah. Segment 61 adjoins unitary segments 65.

Regarding instant claims 23-26, the methods of breaking a pharmaceutical tablet are anticipated by the tablet that may be divided into discrete segments and administered, as taught by Shah (Col. 2, lines 11-20).

Therefore, the limitations of claims 1-3, 5, 12-15, and 21-26 are anticipated by the teachings of Shah.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4, 6-11, 16-17 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Conte et al. (US 6,183,778 B1).

The teaching of Shah with respect to divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet is stated above.

Shah does not expressly teach a first segment that contains either an undetectable amount of a drug, a pharmacologically ineffective amount of drug, or a pharmacologically effective quantity of said drug or drugs present in said second segment, but has fewer milligrams of said drug or drugs relative to the excipients in each segment than does said second segment.

Conte teaches a multi-layer tablet where the first layer contains one or more drugs with immediate or controlled release formulation, the second layer contains one or more drugs with slow release formulation, and a third layer, which is a low-permeability barrier coating (Col. 3, lines 33-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that consists of two layers of drugs and one barrier (non-drug) layer, as taught by Conte, and produce the instant invention.

One of ordinary skill in the art would combine the tablets of Shah and Conte because both references teach the slow or sustained release characteristics of drugs. One of ordinary skill in the art would find it obvious to include the barrier layer in the divisible tablet formulation of Shah in order to optimize the sustained release profile of the chosen active drug.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 4 and 6-9, the limitation of a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of

drug would have been obvious over the barrier layer without any drug, as taught by Conte (Col. 3, lines 33-44 and Col. 6, lines 23-35).

Regarding instant claim 10, the limitation of the first segment that is derived from a granulation that does not contain a drug would have been obvious over the granulation that does not contain a drug for the barrier layer, as taught by Conte (Col. 6, lines 23-35).

Regarding instant claim 11, the limitation of additional unitary segments that are contained in the tablet which are compositionally different from the composition of said first unitary segment and said second unitary segment and are derived from a granulation containing a drug would have been obvious over the compositionally different granulations for layers 4 and 5, as taught by Conte (Col. 6, lines 1-13 and lines 47-61). Layer 4 requires lactose, starch, carboxymethyl starch and cross-linked polyvinylpyrrolidone, which are not required for layer 5. The granulations for layers 4 and 5 contain a drug (ephedrine hydrochloride).

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the two or more discrete segments of the divisible tablet taught by Shah (Col. 2, lines 11-20). One of ordinary skill in the art would find it obvious to include additional segments based on the desired fractions or doses of the whole tablet.

Regarding instant claims 17 and 33, the limitation of the drugs would have been obvious over the non-steroid anti-inflammatory drugs (used for the treatment of pain)

and drugs for the prevention of anginal and hypertensive attacks taught by Conte (Col. 5, lines 6-25).

10. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Addicks et al. (US 5,041,430).

The teaching of Shah with respect to divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet is stated above.

Shah does not expressly teach warfarin as the drug in the tablet.

Addicks teaches a multilayer tablet that comprises warfarin (Col. 7, line 46 to Col. 8, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that comprises warfarin, as taught by Addicks, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17-18, the limitation of warfarin would have been obvious over the warfarin in the multilayer tablet taught by Addicks (Col. 7, line 46 to Col. 8, line 9).

11. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Eberlin et al. (US 3,696,091).

The teaching of Shah with respect to divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet is stated above.

Shah does not expressly teach digoxin as the drug in the tablet.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17 and 19, the limitation of digoxin would have been obvious over the digoxin in the tablet taught by Eberlin (Col. 12, lines 20-45).

12. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 4,824,677) in view of Franz et al. (US 6,555,581 B1).

The teaching of Shah with respect to divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet is stated above.

Shah does not expressly teach levothroxine as the drug in the tablet.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make divisible tablets where the sustained release characteristics of the whole tablet are retained by each segment of the tablet, as taught by Shah, combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the divisible tablet as taught by Shah.

Regarding instant claims 17 and 20, the limitation of levothroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-11, 14-15, 17 and 19 of copending Application No. 11/441,455 (the '455 Application).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference between instant claims and those of the '455 Application is that instant claims require unitary segments. However, one of ordinary skill in the art would find it obvious to design the tablet with unitary segments in order to accomplish partial dosing of the active.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-15 and 20 of U.S. Patent No. 7,329,418 (the '418 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference of immediate release as required by the claims of the '418 patent would have been an obvious variation to one of ordinary skill in the art.

16. Claims 1-26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 6-11 of U.S. Patent No. 7,318,935 (the '935 patent). Although the conflicting claims are not identical, they are

not patentably distinct from each other because the difference of tablet height greater than tablet width as required by the claims of the '935 patent would have been an obvious variation to one of ordinary skill in the art.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615